



added by way of amendment to the drawings. Accordingly, entry of the replacement sheet to the specification of the present invention is respectfully requested.

Claims 1-12, 17, 21, 24-32, 34, 38-40, and 44-46 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 6,017,354 to *Culp* et al., while claims 18, 19, and 23 stand rejected under 35 U.S.C. 103(a) as being unpatentable over the same reference in view of U.S. Patent No. 5,400,267 to *Denen* et al. Claims 20, 24, 37, and 43 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Culp* et al. in view of U.S. Patent No. 6,331,181 to U.S. Patent No. 6,331,181 to *Tierney* et al. Claims 20 and 33 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Culp* et al. in view of U.S. Patent No. 6,298,255 to *Cordero* et al. Lastly, claims 13 and 16 stand rejected under 35 U.S.C. 103(a) as being unpatentable over *Culp* et al. in view of U.S. Patent No. 6,434,507 to *Clayton* et al. These several rejections are respectfully traversed.

Independent claims 1-3, 9, 10, 12, 32, and 44 recite the limitation “a memory disposed in the sheath of the end-effector which optimizes the generator console for operation with the end-effector to achieve optimal tissue effects with the end-effector.” Support for this limitation may be found on page 8, lines 3-6; page 14, lines 14-16; and page 36, lines 4-8 of the specification. Accordingly, Applicants respectfully submit that this limitation does not constitute new matter.

U.S. Patent No. 6,017,354 to *Culp* et al. relates to an integrated surgical tool system for energizing different powered surgical handpieces (see *Abs.*).

Set forth on page 2 thru 3 of the Office Action is the statement that:

An important aspect of Culp's disclosure that the applicant should understand relates to Culp's disclosure of an *ultrasonic surgical hand piece*. First of all, in the BACKGROUND OF THE INVENTION, Culp expresses that the reason for his invention - the problem to be solved - is that with all of

the modern surgical tools now available it is expensive to keep separate generator consoles for each one [Column 1, lines 50-58]. He is setting out to provide a single integrated console that is able to accept tools having many *different power and controls requirements* [Column 3, lines 44-51] that will save time for surgical staff...

Next, Culp discloses *a memory disposed in the sheath (50)* of the end-effector. The sheath (50) could also be called a "grip" or a "handle," as in Claim 2, because the hand piece is held with the user's hand. Memories 72 and 74 are fitted inside of the sheath (50) of the end-effector [see column 6, lines 51-52; Figures 2 and 3]. The console reads information [see column 6, line 65 - column 7, line 1] stored in the memory (72 and 74) to determine whether or not a data string is present. For example, the console reads the memory 72 to check the serial number of the hand piece [Column 15, lines 40-57]. The hand piece can be authenticated for use if the data string (correct serial number, for example) is present....

Set forth on page 7, paragraph 14 of the Office Action is the statement that:

Further, with regards to Claims 1-3, 9, 10, 12, 32, and 44, Culp discloses a memory disposed in the sheath of an end effector, which optimizes operation of the generator console for operation with the end effector to achieve optimal tissue effects with the end effector, as claimed by the Applicant. *Anything that affects the performance of the device will affect its response to/interaction with tissue.* The memory of Culp's device stores data, as previously expounded, and is able to store data associated with the nature of the tissue to be cut with the scalpel. The memory of Culp's device is also able to store performance criteria such as energy level information. This information would help the generator console [and ultimately, the surgeon] *optimize the results of the tissue cutting surgery.... (Emphasis Added)*

For the following reasons Applicants respectfully disagree with the foregoing conclusions. First, *Culp et al.* fails to teach "a memory disposed in the sheath of the end-effector which optimizes the generator console for operation with the end-effector to achieve optimal tissue effects with the end-effector," as set forth and presently claimed.

In this regard, the following is noted. For every blade having different shapes and designations for use on specific types of tissue, there is a desired balance between cutting and hemostasis/coagulation that must be achieved. To accomplish this, for every type of blade design,

the optimal parameters must be found to drive the blade so as to achieve the best tissue effects associated with the application that a blade is designed for. For example, one blade can be designed for use in cutting bowel tissue. In this case, optimization would constitute adjusting the console to drive the blade such that it would cut or coagulate tissue in the most desirable manner.

and that blade would drive in to associated w/ that application

In the claimed invention, the type of blade that is connected to the hand piece is identified by the console. Next, the operational parameters which are appropriate for the blade and tissue that the blade is indicated for are adjusted. In this regard, hemostasis/coagulation refers to the stoppage of an outflow of blood from an incision (e.g., the arrest of bleeding or stagnation of blood) or the causation of the transformation of a liquid or solid into a soft, semi solid or mass (also referred to as coagulation).

The independent claims include the limitation "achieve optimal desired tissue effects." This refers to achieving the optimal balance between the time-to-cut through tissue and the level of hemostasis. Optimal balance is accomplished when the fastest time to cut through tissue is achieved without compromising the level of hemostasis that is achieved. Fast cutting results in poor hemostasis, while slow cutting results in good hemostasis.

Second, with respect to the location of the memory in the *Culp* et al. patent, Applicants wish to draw the Examiner's attention to Fig. 3 of this reference and the exploded view of the internal components of the hand piece motor shown therein. Here, sheath 50 is shown. To understand how the *Culp* et al reference fails to anticipate the claimed invention, Applicants wish to point out that the hand piece in Fig. 2 is shown without an end-effector. As such, the memory referred to in the *Culp* et al. patent is memory units 72 and 74, and they are located in the sheath 50 of the hand piece 32. Further evidence that supports the conclusion that memory 72 and 74 are

located in the sheath 50 of the hand piece 32 may be found in col. 6 lines 51-52 of the *Culp et al* patent (discussing Figs. 2 and 3).

① In contrast, the claimed invention requires the memory to be disposed in the sheath of the end-effector itself, and not in the sheath of the hand piece. The end-effector of the present invention is a device that is attached to one end of the hand piece. This end-effector is used to cut tissue. Again, the memory disclosed and claimed is located in the end-effector. The *Culp et al.* patent simply fail to teach this aspect of the invention that is clearly set forth in each of the independent claims.

The Examiner has stated "*Anything that affects the performance of the device will affect its response to/interaction with tissue*" as a basis for reaching the conclusion that the *Culp et al.* reference teaches the optimization of the generator console for operation with the end-effector to achieve optimal tissue effects. However, Applicants have read the *Culp et al.* reference in its entirety and cannot locate in this reference anything related to the optimization of a generator console so that an end effector is caused to achieve optimal tissue effects. If it is still the Examiner's belief that the *Culp et al.* reference teaches the optimization of the present invention, then Applicant respectfully requests the Examiner point out where in the *Culp et al.* patent such a teaching is shown. In view of the foregoing, Applicants respectfully assert that independent claims 1-3, 9, 10, 12, 32, and 44 are not anticipated by the *Culp et al.* patent and thus, reconsideration and withdrawal of the rejections under 35 U.S.C. §102(b) are respectfully requested.

U.S. Patent No. 5,400,267 to *Denen et al.* relates to a non-volatile memory disposed within electrically powered medical equipment is described (see *Abs.*). According to this patent, the

non-volatile memory may be preprogrammed to store utilization limits and parametric data for the equipment. However, this reference fails to cure the deficiency of the *Culp* et al. patent. Specifically, the *Denen* et al. patent fails to teach “a memory disposed in the sheath of the end-effector which optimizes the generator console for operation with the end-effector to achieve optimal tissue effects with the end-effector,” as set forth in the amended independent claims. As a result, the combination of the *Denen* et al. and *Culp* et al. patent fails to arrive at the present claimed invention.

U.S. Patent No. 6,331,181 to *Tierney* et al. teaches robotic surgical tools, systems, and methods for preparing for and performing robotic surgery include a memory mounted on the tool (see *Abs.*). However, this reference fails to cure the deficiency of the *Culp* et al. patent. Specifically, the *Tierney* et al. patent also fails to teach “a memory disposed in the sheath of the end-effector which optimizes the generator console for operation with the end-effector to achieve optimal tissue effects with the end-effector,” as set forth in the amended independent claims. It follows that the combination of the *Tierney* et al. and *Culp* et al. patents fails to arrive at the present claimed invention.

U.S. Patent No. 6,298,255 to *Cordero* et al. teaches a sensor system which includes a biopotential signal monitor, a smart sensor and the accompanying hardware and software interface which authenticates the source and validity of the smart sensor and also verifies that the smart sensor meets various criteria for use (see *Abs.*). However, this reference fails to cure the deficiency of the combined *Culp* et al. and *Tierney* et al. patents. Specifically, the *Cordero* et al. patent also fails to teach “a memory disposed in the sheath of the end-effector which optimizes the generator console for operation with the end-effector to achieve optimal tissue effects with the end-effector,”

as set forth in the amended independent claims. Accordingly, Applicants respectfully assert that the combination of the *Cordero* et al. and *Culp* et al. patents also fails to arrive at the present claimed invention.

Lastly, U.S. Patent No. 6,434,507 to *Clayton* et al. relates to a system for generating images during medical and surgical procedures that indicate a change in the condition or configuration of a medical instrument being used, wherein the system provides a positive indication of the position of a removable or interchangeable portion of the instrument (see col. 1, lines 19-25). However, even when this reference is combined with the previously cited references, the claimed system is still not achieved. This is because the *Clayton* et al. patent also fails to teach “a memory disposed in the sheath of the end-effector which optimizes the generator console for operation with the end-effector to achieve optimal tissue effects with the end-effector.”

In sum, none of the cited references, neither individually nor in combination, teach or suggest “a memory disposed in the sheath of the end-effector which optimizes the generator console for operation with the end-effector to achieve optimal tissue effects with the end-effector,” as set forth in independent claims 1-3, 9, 10, 12, 32, and 44. In view of this, Applicants respectfully assert that the independent claims are not rendered obvious and unpatentable over the combination of the cited references. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. §103(a) are respectfully requested.

In light of the patentability of independents claim 1-3, 9, 10, 12, 32, and 44, for the reasons above, dependent claims 4-8, 11, 13-31, 33-43, 45-46, and new claim 47 are also patentable over the cited prior art.

Based on the foregoing amendments and remarks, this application should be in condition for allowance. Early passage of this case to issue is respectfully requested. However, if there are any questions regarding this amendment, or the application in general, a telephone call to the undersigned would be appreciated since this would expedite the prosecution of the application for all concerned.

Dated: December 15, 2003

Respectfully submitted,

By 

Alphonse A. Collins

Registration No.: 43,559

DARBY & DARBY P.C.

P.O. Box 5257

New York, New York 10150-5257

(212) 527-7700

(212) 753-6237 (Fax)

Attorneys/Agents For Applicant